REMARKS

Claims 1-22 and 25-38 are pending in the application.

In the outstanding Office Action, claims 1-22, 25-27, 30-34 and 37 were rejected under 35 U.S.C. § 102(b) as being anticipated by U. S. Patent No. 5,380,530 (Hill). This rejection is respectfully traversed. The rejection is predicated on treating the Hill reference as an anticipatory reference. As will be shown, the rejection should be predicated under 35 U.S.C. § 103(a) instead of section 102, because even though one reference is used, the claimed subject matter is not identically disclosed or described in the Hill reference. Thus, a section 102 rejection is improper. Further, since the invention involves unexpected results, even if a *prima facia* rejection under section 103 could be made out, that rejection would be overcome.

The case of *In re Arkley, Erdley, and Long*, 172 USPQ 524 (CCPA 1972) is directly on point. In *Arkley*, the Examiner made a rejection under section 102. The claim at issue was to a compound of a new chemical formula. The prior art reference disclosed a generic class of compounds which included the claimed compound. In addition, two examples (4 and 10) in the cited prior art reference disclosed the precursor of the claimed compound, and there was another teaching in the reference of a chemical reaction which, if applied to the precursor, would yield the claimed compound. However, there was not a direct teaching of applying that reaction to the specific precursor of the examples 4 and 10. Rather, the rejection relied on a statement elsewhere in the reference which arguably taught that the class of compounds would have superior antibacterial activity. Because the rejection was made under section 102, the extensive objective evidence of non-obviousness was disregarded by the Examiner and the Board.

The Court of Customs and Patent Appeals reversed the rejection on section 102 grounds, and the application went back to the Examiner for possible entry of a rejection based on section 103. In making its decision, the court pointed out that the language of Section 103 states that "where the subject matter claimed 'is not *identically* disclosed or described' in 'the prior art'", then section 103 is the proper statutory section for analysis of patentability. Id. at 526 (emphasis in original). The court went on to state, "for the instant rejection under 35 U.S.C. 102(e) to have been proper, the Flynn reference must

clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. Such picking and choosing may be entirely proper in the making of a 103, obviousness rejection, ... but it has no place in the making of a 102, anticipation rejection." Id. (emphasis in original).

In the present rejection based on Hill, one has to pick and choose the various teachings of Hill to come up the claimed invention. Claim 1 requires several things, including a coated chewing gum product, the chewing gum coating including a polyol selected from the group of sorbitol and xylitol, the coating to contain at least one medicament, and a bicarbonate salt incorporated into the chewing gum center, coating or both.

Hill discloses oral hygiene preparations, including coated chewing gum. However, the claimed invention is not identically disclosed. Hill teaches to use a special coating made from an emulsion containing an indigestible surfactant and a polydimethyl siloxane. Optionally the coating may contain a therapeutic substance. Hill goes on to suggest a myriad of possible materials that can be included in the emulsion coating. First, columns 15 and 16 list 18 lines of therapeutic substances, and groups of substances. Following that, Hill states, "Other substances which may also be included in the chewing gum base mixture and which may also be added to the emulsion coating include: non toxic sources for acid such as adipic acid in combination with calcined kaolin, calcium carbonate, sodium carbonate, sodium bicarbonate, various phosphates, dicalcium phosphate, tetra sodium pyrophosphate, lecithin, lanolin, hydrolysable tannin, silica and the like. (Col. 16, lines 6-13). It is thus clear that sodium bicarbonate, required by claim 1 in the present case, is only one of a great many "other substances" that Hill suggests "may also be included." This is certainly not a case where the claimed invention is "identically disclosed or described" in the prior art reference.

Further, when it comes to the two sweeteners specified in claim 1, the reference again lists a myriad of optional ingredients that can be included in the emulsion. Col. 17, lines 7-11 state, "For example, natural and synthetic flavor and sweetener agents as diverse as menthol, xylitol and glycyrrhizin are known to be beneficial towards

plaque control and are included in the emulsion coating compositions of this invention." (Citing two articles).

After discussing other optional ingredients for another 19 lines in column 17, lines 34-39 states, "Additional adjutants[sic] can be added to the emulsion coatings to provide color, flavor, or sweetening effects, as desired. Examples of suitable sweetening agents include sorbitol, sodium cyclamate, saccharine, commercial materials such as NutraSweet® brand of aspartame and xylitol."

There are a full three columns of optional ingredients that can be used in the coating, listing dozens and dozens of different compounds. If one were to list all of the various combinations of the optional ingredients, the permutation of all of the different combinations would likely be millions, if not billions, of different combinations of ingredients suggested for use in the emulsion coating. Yet only a handful of these combinations would have all three of a medicament, sodium bicarbonate and xylitol or sorbitol. Just as in *Arkley*, one has to pick and choose specific optional ingredients from numerous lists of ingredients to come up with all of the items required by claim 1. And, just as in *Arkley*, there are examples in Hill, but none of the examples teach the claimed combination. Nor is there anything in Hill that would make the claimed combination more likely to be used than any other possible combination of optional ingredients.

Hence, just as in *Arkley*, the rejection based on section 102 is not appropriate and should be withdrawn, because Hill does not identically disclose the invention of claim 1.

Claims 16 and 30 require the same three elements identified above in claim 1. Thus these claims, and claims 2-15, 17-22, 25-27, 31-34 and 37 dependent on claims 1, 16 and 30, are not properly rejected under section 102 over Hill.

During a conversation between the below signed attorney and Examiner Corbin on July 19, 2004, Examiner Corbin noted that the specification includes test results that show the unobviousness of the claimed invention, and that is the reason why the case was previously allowed before the Hill reference was considered specifically. In view of the foregoing, it is therefore submitted that even if one could say that Hill, while not directly teaching the claimed invention, made out a *prima facie* case of obviousness, it

is clear that the unexpected results, dramatically increased absorption of caffeine, shown by the test reported in the specification, would overcome such a rejection.

In the outstanding Office Action, claims 28, 29, 35, 36 and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hill in view of U.S. Patent No. 5,487,902 (Anderson) and WO 98/23165 (Gudas). This rejection is also respectfully traversed. The Office Action takes the position that it would have been obvious to substitute caffeine for the benzocaine used in Hill, since both are known to be used as active agents in chewing gum, according to Anderson. However, the reason the benzocaine and caffeine are suggested as alternative ingredients in Anderson has no relevance to Hill. Just because the two ingredients may be alternatively used in Anderson is not a suggestion to use caffeine in Hill. Likewise, just because Gudas teaches different ways of treating caffeine to control its release, there is nothing in the cited references that would suggest using that material in the product of Hill. Further, as indicated above, the present invention involves unexpected results. The additional references do not suggest that the claimed combination would have such dramatic results with respect to bucal absorption. Thus, claims 28, 29, 35 and 36 are patentable for at least the reasons that claims 16 and 35 are patentable. Claim 38 is specifically directed to the use of caffeine, with the same sweeteners and use of sodium bicarbonate as required by claim 1. Thus claim 38 is also patentable over the cited references for at least the same reasons as claim 1.

. Applicants have made a novel and nonobvious contribution to the art of accelerating the absorption of medicaments through the oral mucosa. The claims at issue are distinguish over the cited references and to be in condition for allowance.

Accordingly, a notice of allowance is respectfully requested.

Respectfully Submitted,

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